

## Package leaflet: Information for the user

**Videx 125 mg gastro-resistant hard capsules**  
**Videx 200 mg gastro-resistant hard capsules**  
**Videx 250 mg gastro-resistant hard capsules**  
**Videx 400 mg gastro-resistant hard capsules**

Didanosine

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### **What is in this leaflet:**

1. What Videx is and what it is used for
2. What you need to know before you take Videx
3. How to take Videx
4. Possible side effects
5. How to store Videx
6. Contents of the pack and other information

### **1. What Videx is and what it is used for**

**Videx is an antiviral (or antiretroviral) medicine, used to treat Human Immunodeficiency Virus (HIV) infection.** Videx belongs to a group of medicines called nucleoside reverse transcriptase inhibitors (NRTIs). It is normally used in combination with other anti-HIV medicines.

**Videx is not a cure for HIV infection.** You may continue to develop infections or other illnesses linked to HIV infection. You can still pass on HIV when taking this medicine, although the risk is lowered by effective antiretroviral therapy. Discuss with your doctor the precautions needed to avoid infecting other people.

### **2. What you need to know before you take Videx**

Videx will only be prescribed to you by a doctor with experience in medicines to treat HIV infection.

#### **Do not take Videx**

- **if you are allergic** to didanosine or any of the other ingredients of this medicine (listed in section 6).
- **children younger than 6 years:** Videx gastro-resistant capsules must not be taken by this age group. Other more appropriate didanosine formulations are available.
- **if you are taking stavudine**, used to treat HIV infection.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Videx.

- **if you have or have had pancreatitis** (inflammation of the pancreas), tell your doctor immediately. Symptoms such as stomach pain or abdominal pain might indicate the development of an inflammation of the pancreas. It can become life-threatening if left untreated.

- **if you feel numbness, tingling and pain in the arms and the legs**, tell your doctor. This may be a sign of toxic peripheral neuropathy.
- **taking Videx can cause retinal (eye) or optic nerve changes**, on rare occasions. Your doctor may decide to carry out a retinal examination yearly or if a change in vision occurs.
- **Videx can cause a sometimes fatal condition called lactic acidosis** (excess of lactic acid in your blood) and enlargement of the liver. Symptoms such as nausea, vomiting and stomach pain might indicate the development of lactic acidosis. This rare but serious side effect occurs more often in women, particularly if very overweight or in patients with liver disease. Your doctor will monitor you regularly while you are receiving Videx.
- **if you have or have had problems with your kidneys**, tell your doctor. This is important because Videx is eliminated from your body through the kidneys and you may need a reduced dose.
- **if you have or have had a liver disease, especially chronic hepatitis B or C**, tell your doctor. Some people (including pregnant women) who have taken Videx have had serious liver problems. These problems include hepatomegaly (liver enlargement), steatosis (fat in the liver), liver failure, and portal hypertension (high blood pressure in the large vein of the liver). You may be at an increased risk of severe and potentially fatal liver problems. In rare occasions, patients who have not previously had liver problems can experience liver failure. Your doctor should check your liver function while you are taking Videx. You should be especially careful if you have a history of heavy alcohol use or liver problems.
- **signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started** in some patients with advanced HIV infection (AIDS) and a history of opportunistic infections. It is believed that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms. If you notice any symptoms of infection, tell your doctor immediately. In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment. If you notice any symptoms of infection or other symptoms such as muscle weakness, weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations, tremor or hyperactivity, please inform your doctor immediately to seek necessary treatment.
- during therapy with Videx there is often a gradual loss of subcutaneous fat (fat found beneath the skin), which is most notable in the face and on the legs and arms. Contact your doctor if you notice such changes.
- **some patients taking combination antiretroviral therapy may develop a bone disease called osteonecrosis** (death of bone tissue caused by loss of blood supply to the bone). The length of combination antiretroviral therapy, corticosteroid use, alcohol consumption, severe immunosuppression, higher body mass index, among others, may be some of the many risk factors for developing this disease. Signs of osteonecrosis are joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. If you notice any of these symptoms please inform your doctor.
- **interactions**: it is not recommended to take Videx in combination with tenofovir disoproxil fumarate, hydroxyurea, xanthine oxidase inhibitors (e.g. allopurinol) or ribavirin. This may increase your risk of side effects.
- **do not stop taking Videx without your doctor's advice** because your HIV infection may get worse after stopping treatment.

### Other medicines and Videx

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It is especially important that you inform your doctor if you are already being treated with ganciclovir or valganciclovir. Taking these medicines with Videx may increase the risk of side effects.

Taking Videx with tenofovir disoproxil fumarate, hydroxyurea, xanthine oxidase inhibitors (e.g. allopurinol) or ribavirin is not recommended.

Taking Videx in combination with medicines that are known to cause peripheral neuropathy or pancreatitis may increase the risk of these toxicities. If you take these medicines, your health will need to be carefully monitored.

### Videx with food and drink

Videx is not absorbed well if there is food in the stomach. Therefore, take Videx on an empty stomach at least 2 hours before or 2 hours after a meal.

### Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, tell your doctor to discuss the benefits and risks of your antiretroviral therapy to you and your child. It is not known if Videx is safe to use during pregnancy.

The combination of didanosine and stavudine in pregnant women increases the risk of lactic acidosis.

Breast-feeding is not recommended while taking Videx. Tell your doctor if you are breast-feeding.

### Driving and using machines

No effects on the ability to drive and use machines have been observed.

### Videx capsules contain sodium.

125 mg capsules: Each capsule contains 0.53 mg sodium. Therefore, if you are on a controlled sodium diet, contact your doctor before taking this medicine.

200 mg capsules: Each capsule contains 0.85 mg sodium. Therefore, if you are on a controlled sodium diet, contact your doctor before taking this medicine.

250 mg capsules: Each capsule contains 1.0 mg sodium. Therefore, if you are on a controlled sodium diet, contact your doctor before taking this medicine.

400 mg capsules: Each capsule contains 1.7 mg sodium. Therefore, if you are on a controlled sodium diet, contact your doctor before taking this medicine.

## 3. How to take Videx

- Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. **The capsules must be swallowed whole with a full glass of water.**
- **Do not open or break Videx capsules.**
- Take Videx capsules on an empty stomach at least 2 hours before or 2 hours after a meal. Videx is not absorbed well if there is food in the stomach.

### How much to take

**Not all patients need to take the same dose of Videx.** The usual dose for adults is based on your body weight, as follows:

Your body weight	Total Daily Dose
Less than 60 kg	250 mg, either once daily, or in two 125 mg doses (taken approximately 12 hours apart).
60 kg or more	400 mg, either once daily, or in two 200 mg doses (taken approximately 12 hours apart).

Depending on the side effects you may develop and the diseases you are suffering from at the beginning of your treatment (e.g. pancreatitis, renal impairment), your doctor may prescribe a different dose.

### **Use in children**

**The dose for children older than 6 years will be based on body surface area** which the doctor will calculate. The usual dose is between 120 and 360 mg a day, taken as a single dose, once daily. Videx capsules must not be taken by children under 6 years. Other more appropriate formulations are available for children in this age group.

### **If you take more Videx than you should**

If you have taken more Videx than was prescribed by your doctor, or if someone accidentally takes Videx, contact your doctor or the nearest hospital immediately.

### **If you forget to take Videx**

It is important that you do not miss any doses. If you miss a dose of Videx, take it as soon as possible, but on an empty stomach at least 2 hours before or after a meal, and then take your next scheduled dose at its regular time. However, if it is almost time for your next dose, do not take the missed dose, but wait and take the next dose at the regular time. Do not take a double dose to make up for a forgotten dose.

### **If you stop taking Videx**

Do not stop taking Videx before talking with your doctor. This is very important because the amount of virus may start to increase if the medicine is stopped for even a short time. The virus may then become harder to treat.

**If you have any further questions on the use of this medicine, ask your doctor.**

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Contact your doctor immediately if you feel stomach pain or abdominal pain.** This may be due to inflammation of the pancreas which can become life-threatening if left untreated (see **Warnings and precautions**).

**Tell your doctor if you notice any of the following side effects:**

**Very common side effects** (These are likely to affect more than 1 in every 10 patients)

- **Digestive problems:** diarrhoea

**Common side effects** (These are likely to affect between 1 to 10 in every 100 patients)

- **Liver problems:** hepatitis (inflammation of the liver)
- **Nervous system:** peripheral neurologic symptoms (numbness, weakness, tingling or pain in the arms and the legs), headache
- **Digestive problems:** nausea, vomiting, abdominal pain, flatulence (wind), dry mouth
- **Skin:** rash
- **General:** unusual tiredness or weakness, chills and fever, pain
- **Reproductive system and breast disorders:** breast enlargement in males
- **Metabolism and nutrition:** anorexia
- **Muscles and bones:** muscle pain, joint pain
- **Tests may show:** increased levels of uric acid, increased bilirubin, increased or abnormal levels of some enzymes including liver enzymes in the blood

**Uncommon side effects** (These are likely to affect between 1 to 10 in every 1,000 patients)

- **Digestive problems:** pancreatitis
- **Liver problems:** excess of fat in the liver, liver failure
- **Metabolism and nutrition:** lactic acidosis (excess of lactic acid in the blood), diabetes (starting or getting worse), low or high blood sugar levels
- **Blood:** low red blood cell count, low blood platelet count, lack of white blood cells
- **Muscles and bones:** muscle tenderness or weakness, temporary paralysis or weakness of muscles including kidney disease and haemodialysis
- **Eyes:** dry eyes, changes in colour of the retina, disease of the nerves of the eyes causing blindness
- **Infections:** sore saliva glands
- **Immune system:** sudden life threatening allergic reaction
- **Skin:** alopecia (unusual hair loss or thinning)

**Rare side effects** (These are likely to affect between 1 to 10 in every 10,000 patients)

- **Liver problems:** portal hypertension (high blood pressure in the large vein of the liver)
- **Muscles and bones:** disease of the muscles
- **Digestive problems:** parotid gland enlargement

Treatment with didanosine (Videx) often causes a loss of fat from legs, arms and face (lipoatrophy). This loss of body fat has been shown to be not fully reversible after discontinuation of didanosine. Your doctor should monitor for signs of lipoatrophy. Tell your doctor if you notice any loss of fat from your legs, arms and face. When these signs occur, Videx should be stopped and your HIV treatment changed.

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

**Side effects in paediatric patients are similar to those seen in adults.** Higher blood cells count abnormalities have been reported with the combination with zidovudine. Retinal or optic nerve changes have been reported in a small number of paediatric patients, usually at doses above those currently recommended. Your doctor may decide to carry out a retinal (eye) examination.

**Reporting of side effects** If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

#### **Ireland**

HPRA Pharmacovigilance,  
Earlsfort Terrace,  
IRL Dublin 2  
Tel: +353 1 6764971  
Fax: +353 1 6762517  
Website: [www.hpra.ie](http://www.hpra.ie)  
Email: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

#### **United Kingdom**

Yellow Card Scheme  
Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

### **5. How to store Videx**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister or carton after EXP. The expiry date refers to the last day of that month.

Do not store Videx capsules above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What Videx contains

#### 125 mg capsules

- The active substance is didanosine. Each capsule contains 125 mg didanosine.
- The other ingredients are:  
Capsule content: carmellose sodium, diethyl phthalate, 30% methacrylic acid copolymer dispersion (EUDRAGIT L30D-55), sodium starch glycolate (Type A), talc and sodium hydroxide.  
Capsule shell: gelatin, sodium laurilsulfate and titanium dioxide (E171).  
Capsule shell imprints (edible ink): shellac, propylene glycol, potassium hydroxide, titanium dioxide (E171), yellow and red iron oxide (E172).

#### 200 mg capsules

- The active substance is didanosine. Each capsule contains 200 mg didanosine.
- The other ingredients are:  
Capsule content: carmellose sodium, diethyl phthalate, 30% methacrylic acid copolymer dispersion (EUDRAGIT L30D-55), sodium starch glycolate (Type A), talc and sodium hydroxide.  
Capsule shell: gelatin, sodium laurilsulfate and titanium dioxide (E171).  
Capsule shell imprints (edible ink): shellac, propylene glycol, FD&C Blue #2 Aluminium Lake (E132), titanium dioxide (E171), yellow iron oxide (E172).

#### 250 mg capsules

- The active substance is didanosine. Each capsule contains 250 mg didanosine.
- The other ingredients are:  
Capsule content: carmellose sodium, diethyl phthalate, 30% methacrylic acid copolymer dispersion (EUDRAGIT L30D-55), sodium starch glycolate (Type A), talc and sodium hydroxide.  
Capsule shell: gelatin, sodium laurilsulfate and titanium dioxide (E171).  
Capsule shell imprints (edible ink): shellac, propylene glycol, FD&C Blue #2 Aluminium Lake (E132).

#### 400 mg capsules

- The active substance is didanosine. Each capsule contains 400 mg didanosine.
- The other ingredients are:  
Capsule content: carmellose sodium, diethyl phthalate, 30% methacrylic acid copolymer dispersion (EUDRAGIT L30D-55), sodium starch glycolate (Type A), talc and sodium hydroxide.  
Capsule shell: gelatin, sodium laurilsulfate and titanium dioxide (E171).  
Capsule shell imprints (edible ink): shellac, propylene glycol, ammonium hydroxide, simethicone, red iron oxide (E172).

### What Videx looks like and contents of the pack

#### 125 mg capsules

The gastro-resistant hard capsules are opaque white and embossed in tan with “BMS 125 mg” on one half and “6671” on the other half.

200 mg capsules

The gastro-resistant hard capsules are opaque white and embossed in green with “BMS 200 mg” on one half and “6672” on the other half.

250 mg capsules

The gastro-resistant hard capsules are opaque white and embossed in blue with “BMS 250 mg” on one half and “6673” on the other half.

400 mg capsules

The gastro-resistant hard capsules are opaque white and embossed in red with “BMS 400 mg” on one half and “6674” on the other half.

Videx gastro-resistant hard capsules are supplied in cartons containing 30 or 60 gastro-resistant hard capsules (with 10 hard capsules per blister card).

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **United Kingdom**

Product Licence Holder

Bristol-Myers Squibb Pharmaceuticals Ltd., Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH, England.

Tel: 0800 7311736

#### **Ireland**

Product Authorisation Holder

Bristol-Myers Squibb Pharmaceuticals uc,  
Plaza 254, Blanchardstown Corporate Park 2, Ballycoolin,  
Dublin 15, D15 T867,  
Ireland.

Tel: 01 483 3625

#### **Manufacturer**

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03012 anagni – Frosinone  
Italy

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